

Print date: 11/08/2012

Revision Date: 11/08/2012

Revision Number: 5

1. PRODUCT AND COMPANY IDENTIFICATION

Product Identifier

Product Name:

Ifosfamide for Injection

Product Codes:

CHM1001, CHM1001C, CHM1001P, CHM1002, CHM1002C, CHM1003, CHM1003C, CHM1004, CHM1004C, FCLD140, FKLD140, FKLD140D, FKLD141, FKL141D, FKLD143, FPLD5418, FPLD5428, MX3, 2617B3587, 2617B3588, 55613150, 55613140, 2617B5071, 2617B5072, 57613060, 56613010, 56613120, 55613130, 57613050, SHM1003C, 56610580, 56610590, 55610600, 55610610, 56610280, 57610600, 57610610, 2617B5036, 2617B5037, SHM1001C, SHM1002C, 55613441, 55613141, 2617B5073, 2617B5074, 55610730, 55610740, 56610110, 57610840, 57610850, 55617152, 55617223, 55617224, 57617152, 57617223, HA3001015, 55610050, HA6501048, HA6501049, HA8001174, 26173922, HA8001173, 55613151, 55613142, 55612151, IFOS2, 56610860

Synonyms:

IFEX (Ifosfamide for Injection, USP); Holoxan; Tronoxal

Relevant identified uses of the substance or mixture and uses advised against

Product Use:

Antineoplastic Agent.

Product Type:

Regulated Prescription Drug

Uses advised against:

No information available.

Details of the supplier of the safety data sheet

BAXTER HEALTHCARE CORPORATION

DEERFIELD, ILLINOIS 60015

(800) 422-9837 or (224) 948-4770

E-mail Address

onebaxter@baxter.com

Emergency telephone number

Carechem24 International

+44 (0) 1235 239 670

2. HAZARDS IDENTIFICATION

Label Elements



Signal Word

Warning

Hazard Statements

H302 - Harmful if swallowed

H315 - Causes skin irritation

H317 - May cause an allergic skin reaction

H319 - Causes serious eye irritation

H340 - May cause genetic defects

H350 - May cause cancer

H360 - May damage fertility or the unborn child

H362 - May cause harm to breast-fed children

H372 - Causes damage to organs through prolonged or repeated exposure

Classification of the substance or mixture**REGULATION (EC) No 1272/2008**

Acute Oral Toxicity	Category 4
Skin Corrosion/Irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 2
Skin Sensitization	Category 1
Germ Cell Mutagenicity	Category 1B
Carcinogenicity	Category 1B
Reproductive Toxicity	Category 1B
Effects on or via lactation	Effects on or via lactation
Specific Target Organ Toxicity (Repeated Exposure)	Category 1
Ozone	Not Applicable

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Precautionary Statements

P301+ P310 - IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician

P332 + P313 - If skin irritation occurs: Get medical advice/attention

P362 - Take off contaminated clothing and wash before reuse

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P272 - Contaminated work clothing should not be allowed out of the workplace

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P321 - Specific treatment (see supplemental first aid instructions on this label)

P363 - Wash contaminated clothing before reuse

P202 - Do not handle until all safety precautions have been read and understood

P281 - Use personal protective equipment as required

P405 - Store locked up

P201 - Obtain special instructions before use

P263 - Avoid contact during pregnancy/while nursing

P308 + P313 - IF exposed or concerned: Get medical attention/advice

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P314 - Get medical attention/advice if you feel unwell

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301+ P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents/container to an approved waste disposal plant

Obligatory Precautionary Statements

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

P280 - Wear eye protection/face protection

P321 - Specific treatment (see .? on this label)

P201 - Obtain special instructions before use

P281 - Use personal protective equipment as required

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P202 - Do not handle until all safety precautions have been read and understood

P263 - Avoid contact during pregnancy/while nursing

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

Other Hazards

Indication of Danger: Xn - Harmful.

Risk Phrases:

R45 - May cause cancer.

R46 - May cause heritable genetic damage.

R61 - May cause harm to the unborn child.

R22 - Harmful if swallowed.

R36 - Irritating to eyes.

R48/23/24/25 - Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	EINECS-No.	CAS-No	Weight %	Classification	EU - GHS Substance Classification	REACH No.
Ifosfamide 3778-73-2	223-237-3	3778-73-2	100	Carc. Cat. 2; R45 Mut. Cat. 2; R46 Repr. Cat. 2; R61 T; R48/23/24/25 Xi; R36 Xn; R22	Acute Tox. 4 (H302) Carc. 1B (H350) Repr. 1B (H360) Muta. 1B (H340) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Lact. (H362) Skin Sens. 1 (H317) STOT RE 1 (H372)	No data available

For the full text of the R-phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of first aid measures

General Advice: Treat symptomatically and supportively.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Skin contact: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Most important symptoms and effects, both acute and delayed

May be carcinogenic. May cause allergic skin reaction. See patient package insert in shipping carton for complete information.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable extinguishing media:

Use extinguishing media suitable for surrounding materials.

Extinguishing media which must not be used for safety reasons:

No information available.

Special hazards arising from the substance or mixture

No information available.

Advice for fire-fighters

 Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions

Do not allow material to contaminate ground water system.

Methods and material for containment and cleaning up

Methods for Containment:

If emergency personnel are unavailable, contain spilled material. Absorb with vacuum cleaner approved for carcinogenic substances.

Methods for cleaning up:

Place spilled material in an appropriate container for disposal. Avoid production of dust. Clean contaminated surface thoroughly.

Reference to other sections

See Section 12 for additional information.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Technical

measures/precautions:

Do not ingest. Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures/conditions: Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F). Protect from temperatures above 30°C (86°F).

Incompatible products:

No special restrictions on storage with other products.

Specific End Uses

Other Guidelines:

None

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Limits:

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Component	European Union	United Kingdom	France	Spain	Germany
Ifosfamide 3778-73-2	None	None	None	None	None
Component	Italy	Portugal	Netherlands	Finland	Denmark
Ifosfamide 3778-73-2	None	None	None	None	None
Component	Austria	Switzerland	Poland	Norway	Ireland
Ifosfamide 3778-73-2	None	None	None	None	None

Exposure controls

Engineering measures:

Provide general or local exhaust ventilation. Open handling must be limited.

Personal protective equipment

Eye protection:	Goggles, face shield, or other full-face protection if potential exists for direct exposure to dust.
Hand protection:	Nitrile rubber. Latex gloves.
Respiratory protection:	No personal respiratory protective equipment normally required.
Skin and body protection:	Disposable close-front gown or coveralls.

Environmental Exposure Controls: Do not allow material to contaminate ground water system.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Solid.
Appearance:	Crystalline
Color:	White.
Odor:	Odorless
Odor Threshold:	No information available.
pH:	4.0 - 7.0
Melting point/range:	48-51 °C
Boiling point/range:	No information available.
Flash point:	No information available.
Flammability (solid, gas):	No information available.
Evaporation rate:	No information available.
Flammable limits in air-upper (%):	No information available.
Flammable limits in air-lower (%):	No information available.
Vapor pressure:	No information available.
Vapor Density:	No information available.
Density:	No information available.
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	log Kow = 0.86
Autoignition temperature:	No information available.
Decomposition Temperature:	No information available.
Viscosity:	No information available.
Explosive Properties:	No information available.
Oxidizing Properties:	No information available.

Other information

Molecular weight: 261.1

10. STABILITY AND REACTIVITY

Reactivity

No data available

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

Polymerization: Not applicable
Hazardous Reactions: No information available

Conditions to Avoid

Do not freeze.

Incompatible Materials

Acids. Alkali metals. Oxidizing agents.

Hazardous Decomposition Products

Halogenated hydrocarbons. Organic nitrogenous products of decomposition. Organic compounds of phosphoric compounds.

11. TOXICOLOGICAL INFORMATION

Component	LC50 Inhalation	LD50 Dermal	LD50 Oral
Ifosfamide 3778-73-2	-	-	379 mg/kg (rat)

Information on Toxicological Effects**Acute Toxicity**

Inhalation: Toxic: danger of serious damage to health by prolonged exposure through inhalation. Irritating to respiratory system.

Eye contact: Irritating to eyes.

Skin contact: Toxic: danger of serious damage to health by prolonged exposure with skin. May cause skin irritation.

Ingestion: Harmful if swallowed. Toxic: danger of serious damage to health by prolonged exposure if swallowed. Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness). Renal function effects (may include increased levels of creatinine, BUN, renal failure). Hemorrhagic cystitis.

Irritation: Causes serious eye damage. Causes skin irritation.

Corrosivity: None.

Sensitization: May cause an allergic skin reaction.

Mutagenic effects: Contains a known or suspected mutagen

Carcinogenic effects: Contains a known or suspected carcinogen.

Reproductive toxicity: Contains a known or suspected reproductive toxin. May cause harm to breastfed babies.

STOT - single exposure: No information available

STOT - repeated exposure: Bladder. Bone marrow.

Aspiration Hazard: No information available

12. ECOLOGICAL INFORMATION

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data

Ifosfamide 3778-73-2	None.	None.	None.	None.
-------------------------	-------	-------	-------	-------

Toxicity**Ecotoxicity Effects:**

LC50 (96h): >1000 mg/l; NOEC (96 h): > 555 mg/l Salmo gairdneri; EC50 (48 h): 162 mg/l Daphnia; NOEC (48 h): 100 mg/l Daphnia magna.

Persistence and degradability

Product is not biodegradable.

Bioaccumulative potential

No information available.

Mobility in soil

High mobility in soil.

Results of PBT and vPvB assessment

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Other adverse effects**Endocrine Disruptor Information:**

This product does not contain any known or suspected endocrine disruptors

13. DISPOSAL CONSIDERATIONS

Waste treatment methods**Waste from residues / unused products:**

In accordance with local and national regulations.

Contaminated Packaging:

In accordance with local and national regulations.

14. TRANSPORT INFORMATION

IMDG/IMO

Not regulated

RID

Not regulated

ICAO / IATA:

Not regulated

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
International Inventories**EU EINECS List -**

This product complies with EINECS

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

Chemical Safety Assessment

No

16. OTHER INFORMATION

Full text of R-phrases referred to under Section 3:

R45 - May cause cancer

R46 - May cause heritable genetic damage

R61 - May cause harm to the unborn child

R22 - Harmful if swallowed

R36 - Irritating to eyes

R48/23/24/25 - Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed

Additional information:

Not Available.

Key literature references and sources for data:

www.ChemADVISOR.com/

Prepared by:

Technology Resources, Baxter Healthcare Corporation

Revision Date:

11/08/2012

This data sheet contains changes from the previous version in section(s)?:

New GHS format.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of Safety Data Sheet